



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 30, 2003

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-19

Nicholas H. Jambor, President
Ekone Oyster Company
192 Bay Center Road
South Bend, Washington 98527

WARNING LETTER

Dear Mr. Jambor:

On February 13 and 14, 2003, we inspected your seafood processing facility, located at 378 Bay Center Road, South Bend, Washington. We found that you have a serious deviation from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated, vacuum packaged, smoked oysters are adulterated in that they may have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act, the Seafood HACCP regulation, and the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, through links in FDA's homepage at www.fda.gov.

The deviation was as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR Part 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for refrigerated, vacuum packaged, smoked

Nicholas H. Jambor, President
Ekone Oyster Company, South Bend, Washington
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oysters, does not list the critical control point of smoking for controlling the food safety hazard of *Clostridium botulinum* toxin formation in the final product and pathogen survival.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

We received your letter dated March 19, 2003. That letter indicated that you are working at modifying the smoke chamber to achieve the time and temperature parameters to control *Clostridium botulinum*. You provided no timeline for when you expect this to occur.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations including when you expect the smoke chamber to be modified. You may wish to include in your response documentation such as your revised HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen
District Director

cc: WSDA with disclosure statement